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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,573	07/11/2003	Ellen Filvaroff	P1381R1C1P4C1	8245

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GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER	
JIANG, DONG	
ART UNIT	**PAPER NUMBER**
1646	
MAIL DATE	**DELIVERY MODE**
05/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/617,573	CHEN ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *61,63-66 and 68-86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *76-83 and 86* is/are allowed.

6)☒ Claim(s) *70-75 and 85* is/are rejected.

7)☒ Claim(s) *61,63-66,68,69 and 84* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/6/06 & 10/10/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's amendment filed on 16 January 2007 is acknowledged and entered. Following the amendment, the original claims 62 and 67 are canceled, claims 61, 68 and 72-76 are amended, and the new claims 84-86 are added.

Currently, claims 61, 63-66 and 68-86 are pending and under consideration.

Inventorship

In view of the amendment under 37 C.F.R. §1.48(b) filed on 16 January 2007, the inventorship in this nonprovisional application has been changed by deleting Jian Chen, Sherman Fong, Dorothy French, J. Christopher Grimaldi, Kenneth J. Hillan, Sarah G. Hymowitz, Hanzhong Li, James Pan, Melissa A Starovasnik, Daniel Tumas, Menno Van Lookeren, Richard Vandlen, Colin K. Watanabe, Mickey Williams and Daniel G. Yansura.

Withdrawal of Objections and Rejections:

The objection of the drawings/figures is withdrawn in view of applicant's argument.

All objections and rejections of claims 62 and 67 are moot as the applicant has canceled the claims.

The rejection of claims 61, 64-66, 68, 69, 72-74 and 76-83 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment.

The scope of enablement rejection, and lack of written description rejection of claims 61, 63-66 and 68-75 under 35 U.S.C. 112, first paragraph are withdrawn in view of applicant's amendment.

Formal Matters:

Information Disclosure Statement

The information disclosure statements filed 10 October 2003 and 06 October 2006 are acknowledged, and have been considered. A signed copy is attached hereto.

Claims

Claims 61, 72 and 75 are objected to for the following informalities, appropriate correction is required for each item:

Claims 61, 72 and 75 recite "an antagonist antibody or fragment thereof *of* the polypeptide", "an antagonist antibody or fragment thereof that specifically binds the polypeptide" is suggested.

Rejections under 35 U.S.C. §112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 70 and 71 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 70 and 71 are indefinite because they depend on a canceled claim, claim 67. As such, the metes and bounds of the claims cannot be determined. The applicant may amend the claims to read only upon the pending claims, or to be an independent claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 73 and 74 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the last Office Action mailed on 14 August 2006, at page 5.

Applicants argument filed on 16 January 2007 has been fully considered, but is not deemed persuasive for reasons below.

At pages 11-12 of the response, the applicant argues that the amended claims 73 and 74 recite an "immune inhibiting molecule"(as opposed to an "immunosuppressant"), which is a

broad term encompassing immunosuppressant, and is disclosed in the specification (page 6, line 10; and that it was well-known in the art that methotrexate is an immune inhibiting molecule. This argument is not persuasive because the issue is not whether methotrexate is an immune inhibiting molecule or immunosuppressant, rather, the issue is that the specification never disclosed such a composition comprising the antagonist of the PRO10272 polypeptide *and an immunosuppressant* (claim 73), wherein the immunosuppressant *is methotrexate* (claim 74). The specification merely states, on page 6 (the 2nd paragraph, as pointed out by applicants), "the invention concerns a composition of matter comprising a PRO polypeptide or an agonist or antagonist antibody which binds the polypeptide in admixture with a carrier or excipient; in one aspect, the composition comprises a therapeutically effective amount of the polypeptide or antibody; in another aspect, when the composition comprises an immune stimulating molecule, ..." (indicating the polypeptide or an agonist, for example); "in a further aspect, when the composition comprises an immune inhibiting molecule, ..." (indicating an antagonist antibody, for example). Obviously, the indicated composition comprises an immune stimulating or inhibiting molecule is in context to the composition of matter comprising a PRO polypeptide or an agonist or antagonist antibody, and it does not indicate a composition comprising the combination of a PRO polypeptide or an agonist or antagonist antibody *and* another immune stimulating or inhibiting molecule or immunosuppressant.

This is a new matter rejection.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 72 and 75 remain rejected, and the new claim 85 is rejected under 35 U.S.C. 102(e) as being anticipated by Gorman et al., US6,562,578, for the reasons of record set

forth in the last Office Action mailed on 14 August 2006, at pages 9-10, and for the reasons below.

Applicants argument filed on 16 January 2007 has been fully considered, but is not deemed persuasive for the following reasons.

At pages 13-15 of the response, the applicant argues that the Gorman reference cannot anticipate the present claims under 35 U.S.C. 102(e) as it fails to disclose any information describing in any credible manner any specific biological role, function or activity associated with the IL-174 polypeptide, and thus it does not support the claimed subject matter under 35 U.S.C. 112, first paragraph; and that the absence of experimental data for the IL-174 polypeptide renders the disclosure of Gorman incapable of establishing under 35 U.S.C. 101, a specific, substantial and credible utility for the polypeptide, and thus, the reference fails to satisfy the requirement of §101, and cannot anticipate the present claims. This argument is not persuasive because Gorman teaches how to make the IL-174 polypeptide by discribing the amino acid sequences of the polypeptide, and how to make the antibody thereto. According to 35 U.S.C. 102(e), an anticipating reference needs only to meet the requirement that "the invention *was described* in (1) ... or (2) a patent granted on an application for patent". Further, MPEP indicates, regarding what constitutes enabling prior art for compounds and compositions, that one of ordinary skill in the art must be able to *make* or synthesize (MPEP §2121.02), and that in order to constitute anticipatory prior art, a reference must identically disclose the claimed compound, but *no utility need* be disclosed by the reference. *In re Schoenwald*, 964 F.2d 1122, 22 USPQ2d 1671 (Fed. Cir. 1992) (MPEP §2122). In the instant case, the invention is directed to a product, a pharmaceutical composition of an antibody to the polypeptide of SEQ ID NO:6, which sequence and the antibody to the polypeptide have been disclosed/described in the prior art reference. As such, one of ordinary skill in the art would be able to *make* (or synthesize) the polypeptide and the antibody thereto according to the teachings of the prior art reference. Thus, the prior art reference meets the anticipating requirement of 102(e).

With respect to the limitation of antibody fragment in the new claim 85, Gorman teaches that antibodies including antigen binding fragments and single chain versions (column 41, lines 40-41, and column 42, line 57). Although the reference does not specifically list the antigen binding fragments of the antibody, such (Fab, Fv, Fab2, etc., for example) are well known in the

art, and are exemplified in Example V ("Preparation of antibodies against IL-173") of the Gorman reference as that the antibodies can be further processed, e.g., to Fab, Fab2, Fv or similar fragments (column 52, lines 59-60). Thus, the Gorman reference inherently anticipates claim 85.

Conclusion:

Claims 76-83 and 86 are allowable.

Claim 61 would be allowable if amended to overcome the objections thereto.

Claims 63-66, 68, 69 and 84 are objected to as being dependent upon an objected base claim, but would be allowable if the objected claim is amended to overcome the objections thereto.

Advisory Information:

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

GARY B. NICKOL, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Dong Jiang, Ph.D.
Patent Examiner
AU1646
4/2/07